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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,440	06/23/2000	Wilfried Fischer	2727-110	9975

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,440	FISCHER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. ~~[illegible]~~ 12-16-03.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under Rule 37 CFR §1.114 filed 04/23/04, the Supplemental Response and Applicant's Arguments/Remarks, both filed 06/14/04 is acknowledged.

Claims 1 and 3-10 are pending. Claim 1 has been amended. Claim 2 has been cancelled. Claims 1 and 3-10 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman *et al.* (US Pat. No. 5,538,736).

Hoffman *et al.* teach an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties, wherein the active substance-containing plaster can also contain further additives, such as plasticizers (see reference column 1, lines 20-44), (column 3, lines 17-40); (column 5, lines1-35); (column 8, lines 11-16, 25-57). The active-substance containing plaster contains a back side, a skin side with a back layer, an active substance reservoir which can contain one or more active substances, a contact adhesive device on the skin side and optionally a detachable cover layer, wherein the part of the active substance reservoir part that remains on the skin, has better adhesion to the skin than the back layer (abstract). Hoffmann teaches that apart from the basic materials, the plaster can also contain further suitable additives, such as solubilizers, softeners, plasticizers, tackifiers, stabilizers, fillers and enhancers (col. 8, lines 11-16). The plaster can be used as a transdermal therapeutic system for the controlled administration of medical active substances or also cosmetically active substances to human or animal skin (col. 1, lines 32-43). Figure 1 demonstrates a two-part adhesive active substance-containing reservoir wherein the adhesion of the first active substance reservoir part to the skin must be greater than the adhesion between the peel-off layer and the back layer (col. 4, lines 50-67 through col. 5, lines 1-9). The back layer can be permeable or impermeable and suitable materials for the production thereof are for example, polymeric substances, such as polyethylene and polypropylene. Permeable back layers are, for example, textile fabrics, such as non-woven fabrics, and the like (col. 8, lines 25-38). The detachable protective layer can be made

detachable by applying a silicone layer. Other detachable protective layers are for example, polyvinylchloride, treated paper cellophane, etc. (col. 8, lines 45-53).

Hoffmann teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties. Hoffman does not teach that the layer of adhesive is rendered 'flowable' by the addition of a plasticizer. The phrase ' made flowable' is a future-intended use limitation that holds no patentable weight. Moreover, Hoffmann teaches a plaster comprising suitable additives, which include plasticizers (col. 8, lines 11-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include various suitable additives, particularly plasticizers, because they may serve to affect the bonding or flow properties of adhesion. The expected result would be an active substance-containing plaster for the release of medically active or cosmetically active substances to human or animal skin having distinct or different flowable adhesion properties, as similarly desired by the Applicant.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori (US Pat. No. 5,695,779).

Mori teaches a release controlled transdermal therapeutic system comprising a rubbery adhesive, microcapsules comprising a water-soluble wall material and encapsulating drugs as a core material and a water-insoluble rubber- and rubber solvent-insoluble, water absorbing resin powder, the microcapsules and the resin powder being dispersed in the rubbery adhesive (see Abstract).

Mori, as seen in Figs. 3 and 4, teaches a patch type adhesive preparation wherein the adhesive is applied to a central portion of the base fabric (4) or the release paper (5) to form the adhesive layer (1) having the microcapsule (2) and the water absorbing resin powder (3) dispersed therein, and the adhesive layer (6) which does *not* contain the microcapsules is applied to the remaining portion, such as the circumferential portion of the base fabric (4), or the release paper (5). Alternatively, as seen in Figs. 5 and 6, the adhesive layer which does *not* contain the microcapsules is formed on the base fabric (4) or the release paper (5), and the adhesive layer containing the microcapsule (2) and the water absorbing resin powder (3) dispersed therein is laminated on the adhesive layer (6) (see reference column 6, line 47 – col. 7, line18).

According to Mori, the rubbery adhesive comprises a rubber adhesive component, a tackifier component and a plasticizer component (col. 3, lines 60-62). The rubbery adhesive component includes natural, isoprene, styrene, styrene-butadiene, silicone and acrylic rubbers, for example (col. 3, line 63 – col. 4, line 3). The tackifier component includes, for example, petroleum resins, hydrogenated resins, ester gums, isoprene resins and the like (col. 4, lines 4-15). The plasticizer component includes polybutenes, Vaseline, lanolin, liquid paraffin, higher fatty acid esters, vegetable and animal oils. The rubbery adhesives, tackifier and plasticizer components can be used alone or as a mixture of two or more kinds thereof.

The base fabric is woven fabrics or non-woven fabrics, such as polyvinyl chloride films, polyester films, polyolefin films, laminated films of polyvinyl chloride films and polyester films, polypropylene films or rayon films and films obtained by hot welding the non-woven fabrics on the polyester films or the like (col. 7, lines 32-37). The adhesives can be applied by any coating method, such as hot pressing method, hot melt method or solution coating. For the solution

coating method, suitable solvents include toluene, n-hexane, isohexane, cyclohexane and a volatile oil for rubber (col. 7, lines 19-31).

Mori teaches patch type preparations comprising distinct adhesive layers whereby the microcapsules encapsulating drugs are contained in one area of the adhesive and are not contained or are excluded from the other adhesive area. The teachings of Mori demonstrate a transdermal preparation wherein the active agent is confined to only one area of the adhesive patch. Mori does not explicitly teach that the adhesive is 'made flowable' by a plasticizing additive. However, this is a future-intended use limitation, which without structural limitation affords no patentable weight. Moreover, since Mori explicitly teaches the use of plasticizers in the adhesive preparation, the properties imparted by those plasticizers would also be the same as the properties desired by Applicant. The prior art teaches similar compositions comprising similar components, used in the same field of endeavor and to treat the same problems as that instantly desired. Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 06/14/04 have been fully considered but they are not persuasive.

Applicant argued, "The instant invention is directed to a flat, self-adhering plaster. The plaster has a multi-layer construction and reduced cold flow. The plaster is comprised of a core, wherein the core is the only pharmaceutical or cosmetic active agent area. Hoffman, by contrast, teaches away from such

an invention by requiring at least two drug reservoirs (col. 3, lines 4-6). Hoffman recites the advantages of having two drug reservoirs in col. 3, lines 17-26. Further, Hoffman believes that even three drug reservoirs are advantageous (col. 3, lines 27-30). Thus, a skilled artisan reading Hoffman would be motivated away from practicing the instant invention, wherein the core is the only pharmaceutical or cosmetic active agent area."

These arguments have been fully considered, but were not found to be persuasive. Applicant has amended claim 1 to recite that 'said core *is the only* pharmaceutical or cosmetic active agent area'. Hoffman *et al.*, as delineated above, teach an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties. The active substance-containing plaster contains additives, such as plasticizers (col. 1, L. 20-44), (col. 3, L. 17-40); (col. 5, L.1-35); (col. 8, L.11-16, 25-57). The Applicant argues that more than one reservoir is contained in the plaster of Hoffman *et al.*, whereas in the instant invention the core is the only pharmaceutical or cosmetic active agent area. Burden is shifted to the Applicant to demonstrate that the additional reservoir or additional active agent area in Hoffman *et al.* would be detrimental to the plaster formulation. No unexpected results are observed from the instantly claimed plaster, since the prior art clearly desires and suggests an active substance-containing plaster with distinct adhesion properties.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

November 17, 2004

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